Complete Summary

GUIDELINE TITLE

Practice guidelines for the treatment of tuberculosis.

BIBLIOGRAPHIC SOURCE(S)

Horsburgh CR, Feldman S, Ridzon R. Practice guidelines for the treatment of tuberculosis. Clin Infect Dis 2000 Sep;31(3):633-9. [28 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Tuberculosis (TB), including:

- Active tuberculosis disease
- Latent tuberculosis infection

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Health Plans
Managed Care Organizations
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To present the principles of treatment for either active tuberculosis (TB) disease or latent tuberculosis infection that should be followed to ensure the best outcome for treatment of patients with tuberculosis and for control of tuberculosis in the community

TARGET POPULATION

Patients with active tuberculosis (TB) disease or latent tuberculosis infection

INTERVENTIONS AND PRACTICES CONSIDERED

1. Bacteriologic confirmation and susceptibility testing
2. Respiratory isolation
3. Drug treatment*
    - Isoniazid (INH) + Rifampin (RIF) + Pyrazinamide (PZA) or
    - Isoniazid (INH) + Rifampin (RIF)+ Pyrazinamide (PZA) + Ethambutol (EMB) or
    - Isoniazid (INH) + Rifampin (RIF) + Pyrazinamide (PZA) + Streptomycin (SM)

    *Note from the National Guideline Clearinghouse (NGC): On August 11, 2003, the U.S. Food and Drug Administration, through its MedWatch program, distributed important safety information from the Centers for Disease Control and Prevention (CDC). The CDC notified healthcare professionals of revised recommendations against the use of rifampin plus pyrazinamide for treatment of latent tuberculosis infection, due to high rates of hospitalization and death from liver injury associated with the combined use of these drugs. For more information on this MedWatch alert, please see the U.S. Food and Drug Administration Center for Drug Evaluation and Research (CDER) Web site.

4. Reporting cases to local public health department
5. Re-evaluation of patients with positive sputum smears after 3 months
6. Tuberculin skin testing

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Grades reflecting the quality of evidence on which recommendations are based:

I. Evidence from at least one properly randomized, controlled trial
II. Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one center), from multiple time-series studies, or from dramatic results of uncontrolled experiments
III. Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of recommendation:

A. Good evidence to support a recommendation for use
B. Moderate evidence to support a recommendation for use

C. Poor evidence to support a recommendation
D. Moderate evidence to support a recommendation against use
E. Good evidence to support a recommendation against use

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Excerpted by the National Guideline Clearinghouse (NGC)

Each recommendation includes a ranking for the strength and the quality of evidence supporting it, as well as performance indicators. Definitions of the levels of evidence (I-III) and grades of recommendation (A-E) are repeated at the end of the Major Recommendations field.

Below are listed 8 recommendations for the care and treatment of active tuberculosis (TB) disease and 2 recommendations for the care and treatment of latent tuberculosis infection.

1. Obtain specimens for bacteriologic confirmation and susceptibility testing for patients with tuberculosis or suspected of having tuberculosis (AII).

   Performance Indicator: 90% of adults with or suspected of having tuberculosis have 3 cultures for mycobacteria obtained before initiation of antituberculosis therapy (50% of children 0-12 years)

2. Place persons with suspected or confirmed smear-positive pulmonary or laryngeal tuberculosis in respiratory isolation until noninfectious (AII).

   Performance Indicator: 90% of persons with sputum smear-positive tuberculosis remain in respiratory isolation until smear converts to negative

3. Begin treatment of patients with confirmed or suspected tuberculosis disease with 1 of the following drug combinations, depending on local resistance patterns (AIII):
   - Isoniazid (INH) + Rifampin (RIF) + Pyrazinamide (PZA), or
   - Isoniazid + Rifampin + Pyrazinamide + Ethambutol (EMB), or

- Isoniazid + Rifampin + Pyrazinamide + Streptomycin (SM)

Performance Indicator: 90% of all patients with tuberculosis are started on isoniazid + rifampin + pyrazinamide + ethambutol or streptomycin in geographic areas where >4% of tuberculosis isolates are resistant to isoniazid

*Note from the National Guideline Clearinghouse (NGC): On August 11, 2003, the U.S. Food and Drug Administration, through its MedWatch program, distributed important safety information from the Centers for Disease Control and Prevention (CDC). The CDC notified healthcare professionals of revised recommendations against the use of rifampin plus pyrazinamide for treatment of latent tuberculosis infection, due to high rates of hospitalization and death from liver injury associated with the combined use of these drugs. For more information on this MedWatch alert, please see the U.S. Food and Drug Administration Center for Drug Evaluation and Research (CDER) Web site.

4. Report each case of tuberculosis promptly to the local public health department (AIII).

   Performance Indicator: 100% of persons with active tuberculosis are reported to the local public health department within 1 week of diagnosis.

5. Perform human immunodeficiency virus (HIV) testing for all patients with tuberculosis within 2 months of the diagnosis (AIII).

   Performance Indicator: 80% of all patients with tuberculosis have HIV status determined within 2 months of a diagnosis of tuberculosis

6. Treat patients with tuberculosis caused by a susceptible organism for 6 months, using an American Thoracic Society/Centers for Disease Control and Prevention (CDC)-approved regimen (AI).

   Performance Indicator: 90% of all patients with tuberculosis complete 6 months of therapy within 12 months of beginning treatment

7. Reevaluate patients with tuberculosis who are smear positive at 3 months for possible nonadherence or infection with drug-resistant bacilli (AIII).

   Performance Indicator: 90% of all patients with tuberculosis who are smear positive at 3 months have sputum culture/susceptibility testing performed within 1 month of the 3-month visit

8. Add 2 or more new antituberculosis agents when tuberculosis treatment failure is suspected (AII).

   Performance Indicator: 100% of patients with tuberculosis with suspected treatment failure are prescribed 2 or more new antituberculosis agents

9. Perform tuberculin skin testing on all patients with a history of 1 or more of the following: HIV infection, injection drug use, homelessness, incarceration, or contact with a person with pulmonary tuberculosis (AII).

Performance Indicator: 80% of persons in the indicated population groups receive tuberculin skin test and return for reading

10. Administer treatment for latent tuberculosis infection to all persons with latent tuberculosis infection, unless it can be documented that they received such treatment previously (AI).

    Performance Indicator: 75% of patients with positive tuberculin skin tests who are candidates for treatment for latent tuberculosis infection complete a course of therapy within 12 months of initiation

Definitions of Strength of Recommendation and Quality of Evidence Ratings:

Quality of evidence:

I. Evidence from at least one properly randomized, controlled trial
II. Evidence from at least one well-designed clinical trial without randomization, from cohort or case-control analytic studies (preferably from more than one center), from multiple time-series studies, or from dramatic results of uncontrolled experiments
III. Evidence from opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees

Strength of recommendation:

A. Good evidence to support a recommendation for use
B. Moderate evidence to support a recommendation for use
C. Poor evidence to support a recommendation
D. Moderate evidence to support a recommendation against use
E. Good evidence to support a recommendation against use

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved treatment outcome for patients with tuberculosis (TB) and improved control of tuberculosis in the community.

Subgroups Most Likely to Benefit:

Patients with both tuberculosis (TB) and human immunodeficiency virus (HIV)

POTENTIAL HARMS

Non-adherence to treatment regimen, and drug resistant forms of tuberculosis (TB) are potentially harmful to the patient and the community.

Subgroups Most Likely to Be Harmed:

Patients who are at high risk for treatment failure include (but are not limited to):

- Patients with drug-resistant disease
- Injection drug users
- Alcoholics
- Homeless persons

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Performance indicators are targets for the frequency with which the recommended practices should be followed. These are clearly defined, measurable objectives that are relevant to the recommended practice. Such indicators are useful in evaluating the performance of managed-care plans and other care provider groups with regard to whether minimum performance standards are being met. The benchmark expectation of the frequency with which the recommended practice will be followed has been set in order to allow for variability among sites with regard to the ability to accomplish the action described in the recommendation. Performance indicators are presented with the individual recommendations (see Major Recommendations section).

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Horsburgh CR, Feldman S, Ridzon R. Practice guidelines for the treatment of tuberculosis. Clin Infect Dis 2000 Sep;31(3):633-9. [28 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Sep

GUIDELINE DEVELOPER(S)

Infectious Diseases Society of America - Medical Specialty Society

SOURCE(S) OF FUNDING

Infectious Diseases Society of America (IDSA)

GUIDELINE COMMITTEE

Tuberculosis Committee of the Infectious Diseases Society of America (ISDA)

Infectious Diseases Society of America (IDSA) Practice Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: C. Robert Horsburgh, Jr., Sandor Feldman, and Renee Ridzon

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Infectious Diseases Society of America (IDSA) Web site. Also available in HTML format.

Print copies: Available from the University of Chicago Press; fax: (773) 702-6096.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Kish MA. Guide to development of practice guidelines. Clinical Infectious Diseases 2001;32:851-4.
- Gross PA. Practice guidelines for infectious diseases: Rationale for a work in progress. Clin Infect Dis. 1998 May;26(5):1037-41.
- Gross PA, Barrett TL, Dellinger EP, Krause PJ, Martone WJ, McGowan JE Jr, Sweet RL, Wenzel RP. Purpose of quality standards for infectious diseases. Infectious Diseases Society of America. Clin Infect Dis 1994 Mar;18(3):421.

Electronic copies: Available from the Infectious Diseases Society of American (IDSA) Web site.

Print copies: Available from Infectious Diseases Society of America, 66 Canal Center Plaza, Suite 600, Alexandria, VA 22314.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 1, 2001. The information was verified by the guideline developer as of June 29, 2001.

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